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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,345	08/01/2003	Victor Selig	ST8630US	3729
22203	7590	05/31/2007	EXAMINER	
KUSNER & JAFFE			JOHNSON, EDWARD M	
HIGHLAND PLACE SUITE 310				
6151 WILSON MILLS ROAD			ART UNIT	PAPER NUMBER
HIGHLAND HEIGHTS, OH 44143			1754	
			MAIL DATE	DELIVERY MODE
			05/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/633,345	SELIG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Edward M. Johnson	1754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 March 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 3-6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The added recitation specifying "a sealable container" and "a microbial barrier" do not appear to be supported by the original disclosure. However, Applicant is invited to point out where such specific support may be found.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the

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invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 4-6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Halstead et al. US 6,919,057.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 4, Halstead '057 discloses a method of cleaning and disinfection of devices comprising:

- a) placing the items into a rack within a container having sealing members, a cavity, and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures),
- b) placing the container into a reprocessor (abstract), thus engaging the ports,

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c) pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract),  
d) removing the rack and container from the reprocessor (see column 11, lines 31-34), which would inherently store the items therein until removed.

The disclosed container would inherently provide a microbial barrier.

When the examiner has reason to believe that the functional language asserted to be critical for establishing novelty in claimed subject matter may in fact be an inherent characteristic of the prior art, the burden of proof is shifted to Applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied upon. In re Fitzgerald et al. 205 USPQ 594. As a practical matter, the Office is not equipped to manufacture or obtain products and make resulting comparisons with the claimed invention. Where, as here, the burden has been shifted to applicant, it is appropriate to make a rejection based upon §102 as well as §103.

Regarding claim 5, Halstead '057 discloses liquid (abstract).

Regarding claim 6, Halstead '057 discloses a heated air-drying step (see column 12, lines 10-13).

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halstead '057.

Regarding claim 1, Halstead '057 discloses a method of cleaning and disinfection of devices comprising:

- a) placing the items into a rack within a container having a cavity and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures),
- b) placing the container into a reprocessor, thus engaging the ports,
- c) pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract),
- d) removing the rack and container from the reprocessor (see column 11, lines 31-34), which would store the items therein until removed.

Halstead fails to disclose causing the container to assume the closed position at removal.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to cause the container of Halstead to assume the closed position because Halstead discloses a leak test after reprocessing to ensure an endoscope is not damaged during reprocessing (see column 12, lines 27-30), which would motivate an ordinary artisan to close the container upon the disclosed removal of the container to advantageously avoid damage of the item to be reprocessed. The obvious closed position would also provide a microbial barrier.

Regarding claim 2, Halstead '057 discloses removing the rack and container from the reprocessor (see column 11, lines 31-34), which would store the items therein until removed.

Regarding claim 3, Halstead '057 discloses a heated air-drying step (see column 12, lines 10-13).

***Response to Arguments***

7. Applicant's arguments filed 3/8/07 have been fully considered but they are not persuasive.

It is argued that it is respectfully submitted that none... or the advantages thereof. This is not persuasive because the disclosed container of the prior art would inherently provide a microbial barrier (see rejection, above).

It is argued that in response to the Examiner's rejections... around said items. This is not persuasive for the reasons above and also because the recitation is new matter.

It is argued that Halstead et al. '057 discloses... the '057 reference. This is not persuasive for the reasons above.

It is argued that the Examiner states in step a) that... 82 passes (Fig. 7). This is not persuasive for the reasons above and because Applicant appears to admit that a portion of the item is placed within the container.

It is argued that the Examiner also states that the "ports" disclosed... '057 patent. This is not persuasive because the Figure clearly discloses a reprocessor with fluid access ports that are to be engaged. Whether the patent refers to these ports as "outlets", as Applicant appears to suggest, would not be a patentable distinction.

It is argued that the Examiner states in step d) that... therein until removed. This is not persuasive because because the disclosed container of the prior art would inherently provide a microbial barrier and the recitation is new matter (see rejection, above).

It is argued that the Examiner also states that it "would have been obvious... reprocessing (see column 12, lines 27-30)." This is not persuasive because Applicant appears to admit that a

leak test on the endoscope is disclosed and it would have been within the purview of an ordinarily skilled artisan to put the container in a closed position to avoid leaking similar reasons.

**Conclusion**

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward M.

Johnson whose telephone number is 571-272-1352. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley S. Silverman can be reached on 571-272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Edward M. Johnson  
Primary Examiner  
Art Unit 1754

EMJ